IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Daniel Resnic**	Examiner: Ostrup, Clinton T.
Application No. 10/681,076	Confirmation No. 7675
Filed:10/07/2003	Art Unit: 3771
	Docket No. 09-07-5207
Title: Universal Unisex Safety Condom	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DANIEL RESNIC IN SUPPORT OF AMENDMENT AND RESPONSE TO FINAIL OFFICE ACTION DATED MARCH 6, 2009 AND REQUEST FOR CONTINUED EXAMINATION

I, the undersigned Daniel Resnic, hereby make the following declaration:

1. I am the inventor of the Universal Unisex Safety Condom that is the subject of Application No. 10/681,076.

2. I am also the Founder and CFO of Strata Various Product Design, a product design firm that is involved with inventions and patents of consumer utility devices, including the AI and RAI ORIGAMI Condoms, which are non-latex, silicone condoms.

3. I am the inventor of a silicone rubber condom, which is planned for clinical

research with the Women's Global Health Imperative at RTI, in San Francisco, in collaboration with its director, Dr. Arianne van der Straten. A related silicone rubber condom has been funded by the National Institutes of Health (NIH) with a $1.1 Million grant from the National Institute of Allergies & Infectious Diseases (NIAID) for clinical research in collaboration with co-Investigator, Dr. Pamina Gorbach, head of the Behavioral Epidemiology Research Group (BERG) at UCLA's Department of Epidemiology.

4. I have researched characteristics that had prevented latex condoms from being used as extensively and consistently as needed to curtail the HIV epidemic. After a year-long investigation, I identified several key areas where design solutions could have a marked effect on consumer satisfaction:

- Creating a barrier that does not diminish sensitivity;
- Improving fit and reducing constriction of the glans;
- Creating a condom that is easier and quicker to don (less interruption of sexual intimacy);
- Reducing slippage by designing a means of securing the condom;
- Reducing breakage by searching for a more durable alternative to latex and plastic;
- Finding an alternative, biocompatible material that is acceptable to consumers with latex allergy.

5. I determined that latex formulations could not achieve the characteristics I was seeking. Consequently, I investigated alternatives and selected silicone as the candidate material. It is biocompatible for internal contact with human tissue.

6. To address the problem of diminished sensation, the latex condom industry has traditionally opted for thinner materials. In stark contrast, the silicone condom is a thicker, heavy gauge condom, which has a life-like feel of human tissue that can *create* the desired sensation instead of acting as a *barrier to* sensation. The heavy gauge design not only resolved diminished sensation, but,

at the same time, it reduced the likelihood of condom breakage.

7. The silicone condom can elongate to 1100% of its original size and feels like human tissue to the touch.

8. The silicone rubber condom also features a radical, shape-retaining design that provides faster and easier application than the rolled latex condom.

9. The Center for Scientific Review, which evaluates the funding applications to the National Institutes of Health, awarded $212,000 to study the silicone rubber condom. Attached hereto as **Exhibit 1** is a true and correct copy of an evaluation report on the silicone rubber condom by the Center for Scientific Review, finding:

> It is highly significant in proposing to develop a condom that will potentially have a higher acceptance rate than the latex condom. Two primary benefits are advanced for silicone rather than latex: that it may provide better sensation and that it will be less prone to breakage. There would be a high level of significance to developing a condom with these characteristics if it led to increased condom use.
>
> ***
>
> Innovation: The proposal is highly **innovative** with respect to the material for condoms as well as design.
>
> ***
>
> **Significance:** As stated by the author, condoms used correctly and consistently are the most effective method available to reduce the risk of transmitting STI's including HIV. However, many find latex condoms unappealing and unacceptable for multiple reasons including lack of sensation and latex allergies. This product would provide an alternative that would be stronger than latex condoms yet provide better sensation. The overall goal of this project is to refine and test a prototype of the ORIGAMI Condom, a new condom made from silicone.

> ***
>
> Innovation: This product, if proven acceptable for human use could **revolutionize the male condom** with respect to enjoyment while providing protection from disease and pregnancy.

10. After producing hundreds of design iterations, I filed for a U.S. patent for the novel silicone condom. The new condom was designed to meet FDA performance standards, and has exceeded that in many pre-clinical tests. The viral barrier evaluation test resulted in zero viral permeability compared with 5% failure of the leading latex condom. Attached hereto as **Exhibit 2** is a true and correct copy of a Condom Barrier Evaluation Study conducted by Nelson Laboratories showing the silicone condom resulted in zero viral permeability compared with 5% failure of the leading latex condom.

11. Preliminary structural tests indicate a high tolerance for heat and exposure to sunlight, unlike its latex counterpart. Sample prototypes were boiled in water, soaked in bleach, washed in an automatic washer, dried in a commercial dryer and even sterilized in a microwave, retaining its structural integrity. None of these attributes are attainable with a condom made of latex or of any other conventional material, such as nitrile or polyurethane

12. Attached hereto as **Exhibit 3** is a true and correct copy of a Test Report on the Dimensions and Tensile Properties of Rubber Condoms conducted by Nelson Laboratories.

13. Attached hereto as **Exhibit 4** is a true and correct copy of a letter from the California Family Health Council, Inc. regarding clinical testing of the silicone rubber condom.

14. Attached hereto as **Exhibit 5** is a true and correct copy of a letter from

Prof. Pamina M. Gorbach, PhD (Dept. of Epidemiology, UCLA), stating: “The Origami RAI Condom™ is **innovative** and potentially acceptable for AI use, **considering the durable, heavy gauge silicone material they are made of. It could offer a viable alternative to latex condoms** that may be more compatible with AI, and therefore, **provide much needed other method of HIV protection**.”

15. Attached hereto as **Exhibit 6** is a true and correct copy of a letter from Dr. Alen Voskanian (David Geffen School of Medicine, UCLA), stating: “[T]he Origami RAI Condom [is]…a unique condom concept specific for AI use. It has the potential to provide an improved option for AI than the traditional latex condom, which is not designed or FDA approved for AI use.”

16. Attached hereto as **Exhibit 7** is a true and correct copy of a letter from Reeshemah B. Chatham (Senior Scientist, Bluestar Silicones Corp.), stating: “Congratulations on the successful Phase I study results for the ORIGAMI RAI Condom™ using the ORIGAMI Elastomer™ Silicone we helped develop for you. As we’ve discussed, latex sensitization and allergies have been a public concern for years, especially for health care workers and atopic individuals. With an estimated 1.3% of the US population being sensitized by latex products…., much work has been invested in finding alternative chemistries that will provide similar, if not better, performance characteristics without the health risks.”

17. Attached hereto as **Exhibit 8** is a true and correct copy of a letter from Adam Glickman (CEO, Condomania®), stating: “**Consumer demand** from both women and men who engage in AI has been extremely high for a better alternative to the latex condom with fewer performance issues during AI use….**The Origami Condoms™ have addressed several of the most important design challenges that could not otherwise be resolved with the rolled latex condom.** The **viral impermeable** ORIGAMI ELASTOMER™ material you’ve developed is unmatched in the condom industry anywhere in the

world. I have also reviewed your pre-clinical testing data for the Origami Male Condom™, conducted by Nelson Labs, and **its impermeability to virus smaller than HIV is highly significant, especially when considered in context with the simultaneous comparison tests they conducted with the Trojan® latex condom that validates 5% failure in its viral barrier evaluation….**I have reviewed your preliminary data for this unique ORIGAMI ELASTOMER™ material, which verified its **tolerance of temperatures up to 425ºF, making its reusability potential a viable probability.**"

18. Attached hereto as **Exhibit 9** is a true and correct copy of a letter from Ariane van der Straten, PhD, MPH (Senior Research Scientist, Associate Director of Women's Global Health Imperative), stating: "I am writing to offer my wholehearted support for the [Origami Female Condom™] … a new condom made of silicone, a material that may provide better sensation and be less prone to breakage and slippage than latex or plastic, in addition to its viral impermeability."

19. Attached hereto as **Exhibit 10** is a true and correct copy of a letter from Dennis Bui (Engineer), stating: "As you are aware from your pre-clinical testing of he male condom made of ORIGAMI Elastome[r]-0134™, **it is superior to latex in almost every aspect of its strength** (tensile strength, elongation, tear strength) and its biocompatibility. Hospitals worldwide have been working towards a latex-free environment for years."

I hereby declare that all statements made herein are to the best of my knowledge and that all statements made on information and belief are believed to be true.

Daniel Resnic

September 3, 2009 Daniel Resnic